Ondansetron for the prevention and treatment of nausea and vomiting following pediatric strabismus surgery


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of intravenous (0.1 mg/kg) plus oral ondansetron (0.15 mg/kg every 8 hours when needed) for the prevention and treatment of nausea and vomiting. This was compared to treatment with intravenous droperidol (0.05 mg/kg) plus oral dimenhydrinate (1.25 mg/kg every 8 hours when needed).

Type of intervention

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged 6 months to 18 years who were undergoing strabismus surgery. The exclusion criteria were nausea or vomiting, or the use of anti-emetics or narcotics in the 24 hours preceding surgery. Patients with a past history of hepatic, gastric or renal disease were also excluded.

Setting
The setting was secondary care (a paediatric hospital). The economic analysis was conducted in Montreal, Canada.

Dates to which data relate
The effectiveness data were collected from November 13th 2000 to June 12th 2001. The dates to which the resource data related were not reported. The price year was also not reported.

Source of effectiveness data
The effectiveness data were derived from a single prospective study.

Link between effectiveness and cost data
The costing was carried out on a theoretical patient weighing 25 kg.

Study sample
No power calculations to determine the sample size were reported. All of the patients who met the inclusion criteria were included in the study. Patients who refused to participate or were unable to give consent were excluded. Of the 208 eligible patients, 36 were excluded. Seventeen of these refused to participate, while in 12 cases there were logistical problems. A total of 172 patients were randomly assigned to the study groups. There were 88 in the ondansetron group and 84 in the droperidol-dimenhydrinate group.
Study design
The study was a double-blind, randomised clinical trial that was conducted in a single centre. The patients were randomised according to pre-determined allocation lists. The allocation does not appear to have been concealed from the surgeons. There does not seem to have been any blinding. The duration of follow-up was unclear, but it is likely to refer to the time period after surgery and until the first 24 hours at home. No loss to follow-up was reported for patients while in hospital. However, 5 patients were lost from each group for the follow-up outcomes at home.

Analysis of effectiveness
All of the patients were accounted for in the analysis of outcomes measured at the hospital. However, the analysis for outcomes measured at home was only carried out on those for whom data were available. The primary health outcomes used in the analysis were the frequency of nausea and vomiting, severity of nausea (on a scale from 0 to 3) and adverse effects (e.g. headache, dizziness, constipation). Nausea and vomiting were measured in hospital, during transportation home and after discharge (up to 3 hours, 3 to 6 hours, 6 to 12 hours, and 12 to 24 hours). The data were obtained from nursing notes and through a telephone interview conducted 24 to 48 hours after discharge. The two treatment groups were comparable in terms of their demographic and perioperative features. These variables were compared between patients who experienced nausea and vomiting and those who did not.

Effectiveness results
There was no statistically significant difference between the ondansetron and droperidol-dimenhydrinate groups in the incidence of nausea (49.4% versus 55.1%), severe nausea (14.4% versus 15.4%), (p=1.00), or vomiting (25.3% versus 31.6%), (p=0.371), in hospital and at home. The difference between the two groups in the incidence of adverse effects (32.5% versus 22.8%) was also not statistically significant, (p=0.220).

The difference between the two groups in the rate of vomiting during transportation home, 3.6% (ondansetron) versus 12.6% (droperidol-dimenhydrinate), was significant, (p=0.044).

Patients who vomited at least once had a longer mean duration of anaesthesia (56 +/- 17 minutes) than those who did not experience any vomiting (49 +/-11 minutes), (p=0.004).

Patients with severe nausea (score 3) had a longer mean duration of anaesthesia (58 +/- 15 minutes) than those who experienced no or less nausea (50 +/-13 minutes), (p=0.01).

Clinical conclusions
No significant difference was observed between the two groups in the incidence of nausea and vomiting and in the length of hospital stay.

Measure of benefits used in the economic analysis
There was no summary measure of benefit in the economic analysis. A cost-consequences analysis was therefore conducted.

Direct costs
The perspective adopted in the analysis was unclear. The costing was carried out on a theoretical patient weighing 25 kg. The direct costs to the hospital were included, such as drug acquisition costs (anti-emetics used), per diem costs, and the length of hospital stay. The methods used to evaluate the costs and quantities of resources were not described. The costs and the quantities were not reported separately and no price year was given. The source of the quantity/cost data was not reported. Discounting was unnecessary.

Statistical analysis of costs
No statistical analysis of the costs was carried out.

**Indirect Costs**
No indirect costs were included in the analysis.

**Currency**
Canadian dollars (Can$).

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The combination of droperidol-dimenhydrinate (Can$16.76) was seven times less costly for a theoretical patient weighing 25 kg than the ondansetron regimen (Can$119.50).

**Synthesis of costs and benefits**
Not applicable.

**Authors' conclusions**
Treatment with intravenous and oral ondansetron was not cost-effective given the lack of differences in the incidence of nausea and vomiting and in the length of hospital stay between the two groups, and the higher costs of the ondansetron regimen.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the comparator used. The comparator, droperidol plus dimenhydrinate, was the standard pharmacological treatment after strabismus surgery in the authors' setting. You should consider whether this is a widely used technology in your own setting.

**Validity of estimate of measure of effectiveness**
The estimate of effectiveness was derived from a randomised controlled trial. However, there was no mention of concealment of allocation or blinding and power calculations were not reported. There was no evidence that the study sample was representative of the study population, especially since some patients refused to participate. The patient groups were shown to be comparable at analysis, suggesting a low risk of confounding factors. Appropriate statistical analyses were performed to ensure the accuracy of the comparison.

**Validity of estimate of measure of benefit**
The analysis of benefits was based upon the therapeutic equivalence of treatment alternatives. Consequently, a cost-consequences analysis was performed.

**Validity of estimate of costs**
The perspective adopted was unclear, but it is likely to have been that of the hospital. The costs and the quantities were
not reported separately. Also, the methods used to evaluate the costs and quantities of resources were not described. The source of the quantity/cost data was not reported, but it is likely that the unit costs were estimated using actual data. No price year was stated. No statistical analysis of the costs was carried out. These facts may limit the interpretation and the generalisability of the study findings.

Other issues
The generalisability of the results to other settings or countries was not discussed. Adequate comparisons were made with studies dealing with the same topic. The study enrolled children undergoing strabismus surgery and this was reflected in the authors’ conclusions. The authors did not report any limitations of their study. They do not appear to have reported their results selectively. The main limitation of this study was the cost analysis, for which few details were reported.

Implications of the study
The authors suggested that the use of ondansetron could be limited to patients predisposed to motion sickness or to postoperative nausea and vomiting, or who reside at a greater distance from the hospital.

Source of funding
None stated.

Bibliographic details

PubMedID
12733689

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Administration, Oral; Antiemetics /economics /therapeutic use; Child; Child, Preschool; Dimenhydrinate /economics /therapeutic use; Double-Blind Method; Droperidol /economics /therapeutic use; Drug Costs; Drug Therapy, Combination; Female; Humans; Injections, Intravenous; Male; Nausea /drug therapy /economics /prevention & control; Ondansetron /economics /therapeutic use; Postoperative Complications /drug therapy /economics /prevention & control; Prospective Studies; Safety; Strabismus /surgery; Vomiting /drug therapy /economics /prevention & control

AccessionNumber
22003000788

Date bibliographic record published
31/01/2004
Date abstract record published
31/01/2004